UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------------|----------------------|---------------------|------------------|
| 10/667,248 | 09/17/2003 | Michael Adam | ZIM0590 | 1126 |
| 832 7590 12/05/2008 BAKER & DANIELS LLP | | | EXAMINER | |
| 111 E. WAYNI | ·- | HOFFMAN, MARY C | | |
| | SUITE 800 FORT WAYNE, IN 46802 | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/05/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|-----------------------|--|--|--|--|
| | 10/667,248 | ADAM, MICHAEL | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | MARY HOFFMAN | 3733 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 12 Se | eptember 2008 | | | | | |
| , <u> </u> | | | | | | |
| <i>,</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-9,11-13,15,17-24 and 26-28</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) <u>2-9,18-20,23,24 and 26-28</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>1,11-13,15,17,21 and 22</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| ·— · · · — · | election requirement | | | | | |
| o) Olaim(s) are subject to restriction and/or | 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)⊠ The drawing(s) filed on <u>17 September 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) \[\sum \text{Notice of References Cited (PTO-892)} \] 4) \[\sum \text{Interview Summary (PTO-413)} \] | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. Solution of Informal Patent Application | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/14/2008. 5) Notice of Informal Patent Application 6) Other: | | | | | | |
| 1 apor 110 (0) milan batto 1111112000. | | | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11-13, 15, 17, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shavit et al. (IL147783D DO, published 8/14/2002, see corresponding US Patent Application Publication 2005/0069397) in view of Buhler (US 6,702,816, cited by Applicant).

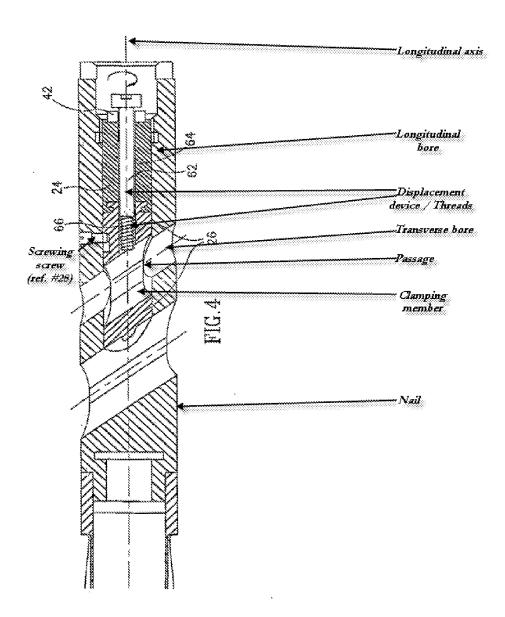
Shavit et al. disclose a bone fixing system comprising a nail, the nail comprising a longitudinal axis, a longitudinal bore defining an inner wall of the nail, and a transverse bore defining a longitudinal axis, and a cross-fastener, which can be guided through the transverse bore formed in the nail, the transverse bore being configured so as to define a spatial orientation and a position of the cross-fastener with respect to the longitudinal axis of the nail, wherein the spatial orientation and position imposed on the cross-fastener guided through the transverse bore in three dimensions, the bone fixing system further comprising at least one clamping member which can be introduced into the longitudinal bore and is axially adjustable in the longitudinal bore relative to the nail, with the screw guided through the transverse bore being able to be clamped between the at least one clamping member and the inner wall of the nail bounding the transverse bore

Application/Control Number: 10/667,248 Page 3

Art Unit: 3733

by a displacement of at least one clamping member. The bone fixing system further comprises a displacement device arranged and adapted for effecting a pulling force on a clamping member, wherein a section of the clamping member disposed on a side of a screw remote from the displacement device can be moved against the cross-fastener by the pulling force. The clamping member when inserted is freely movable at least in the axial direction within the longitudinal bore of the nail and comprises a passage aligned with the transverse bore of the nail. The displacement device includes a drawing screw which cooperates with a thread The clamping member is adapted to be deformed in the axial direction by means of the displacement device. A securing member which can be moved through a side wall of the nail into the longitudinal bore and by which the clamping member can be fixed in a starting position relative to the nail prior to the actuation of the displacement device; the securing member is a securing screw (ref. #28). The transverse bore is essentially circular in cross section.

Art Unit: 3733



Shavit et al. disclose the claimed invention except for multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, i.e. three transverse bores/passages and three screws.

Page 5

Art Unit: 3733

Buhler discloses using multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, i.e. three transverse bores/passages and three screws, in order to achieve better anchoring.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the nail of Shavit et al. with multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, i.e. three transverse bores/passages and three screws in view of Buhler in order to achieve better anchoring. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Shavit et al. with a plurality of transverse bores formed in the nail and a plurality of passages formed in the clamping member, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Claims 1, 11-13, 15, 17, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grammont (US 5,074,882) in view of Buhler (US 6,702,816, cited by Applicant).

Grammont discloses a bone fixing system comprising a nail (ref. # 1, FIGS. 2-3), the nail comprising a longitudinal axis, a longitudinal bore defining an inner wall of the nail, and a transverse bore (see bottom of FIG. 3) defining a longitudinal axis, and a cross-fastener (ref. #9), which can be guided through the transverse bore formed in the nail, the transverse bore being configured so as to define a spatial orientation and a position of the cross-fastener with respect to the longitudinal axis of the nail, wherein the Art Unit: 3733

spatial orientation and position imposed on the cross-fastener guided through the transverse bore in three dimensions, the bone fixing system further comprising at least one clamping member (ref. #5) which can be introduced into the longitudinal bore and is axially adjustable in the longitudinal bore relative to the nail, with the screw guided through the transverse bore being able to be clamped between the at least one clamping member and the inner wall of the nail bounding the transverse bore by a displacement of at least one clamping member. The bone fixing system further comprises a displacement device (ref. #2) arranged and adapted for effecting a pulling force on a clamping member, wherein a section of the clamping member disposed on a side of a screw remote from the displacement device can be moved against the crossfastener by the pulling force. The clamping member when inserted is freely movable at least in the axial direction within the longitudinal bore of the nail and comprises a passage aligned with the transverse bore of the nail. The displacement device includes a drawing screw (ref. #3) which cooperates with a thread The clamping member is adapted to be deformed in the axial direction by means of the displacement device. A securing member (ref. #8) which can be moved through a side wall of the nail into the longitudinal bore and by which the clamping member can be fixed in a starting position relative to the nail prior to the actuation of the displacement device; the securing member is a securing screw. The transverse bore is essentially circular in cross section.

Grammont discloses the claimed invention except for multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, *i.e.* three transverse bores/passages and three screws.

Buhler discloses using multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, *i.e.* three transverse bores/passages and three screws, in order to achieve better anchoring.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the nail of Grammont discloses with multiple transverse bores/passages and screws in different spatial orientations and positions in three dimensions, *i.e.* three transverse bores/passages and three screws in view of Buhler in order to achieve better anchoring. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Grammont with a plurality of transverse bores formed in the nail and a plurality of passages formed in the clamping member, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments filed 09/12/2008 have been fully considered but they are not persuasive.

Shavit et al. (IL147783D DO) in view of Buhler (US 6,702,816)

Applicant argues that "Shavit '397 discloses a locking mechanism for use with an intramedullary nail that includes bore 32 that is specifically sized to prevent the locking in position of a hip pin, such as hip pin 25 of Fig. 5A" on page 8. In response to applicant's argument that the clamping member and passage of Shavit is directed

Application/Control Number: 10/667,248

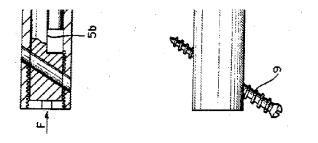
Art Unit: 3733

towards preventing locking of the pin, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It appears from the structure of the clamping member and passage of Shavit that one would be capable of locking or clamping the transverse pin with the nail by displacing the clamping member relative the nail.

Page 8

Grammont (US 5,074,882) in view of Buhler (US 6,702,816)

Applicant argues that "nowhere does Grammont '882 disclose or suggest that the displacement of rod 5 clamps a screw between rod 5 and nail C." As seen in the below figure from Grammont, the inner rod 5 (the claimed "clamping member") can be displaced up and down relative the outer nail. When screw 9 is inserted into the outer nail and inner rod, and the inner rod is subsequently displaced relative the outer nail, the screw will be clamped between the inner rod and the outer nail due to this displacement. Therefore, Grammont meets the claim language that requires the screw be clamped between the clamping member and the inner wall of the nail bounding the transverse bore by a displacement of the clamping member, since displacement of inner rod 5 relative the outer nail will result in this clamping action.



It is again noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The above rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is

Application/Control Number: 10/667,248 Page 10

Art Unit: 3733

(571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/ Examiner, Art Unit 3733 /Eduardo C. Robert/ Supervisory Patent Examiner, Art Unit 3733